

**REMARKS**

Claims 1 and 3-21 were pending in the present application. No claims are currently canceled or added. Accordingly, claims 1 and 3-21 are currently pending in the present application.

Reconsideration of this application in light of the above amendments and the following remarks is requested.

**Rejections under 35 U.S.C. §112**

Claim 1

Claim 1 was rejected under 35 U.S.C. §112, first paragraph, for having a non-enabling disclosure and failure to comply with the written description requirement. Claim 1 was also rejected under 35 U.S.C. §112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements. The Examiner bases these rejections on the lack of a reflecting element being disclosed in claim 1. However, paragraph [0019] discloses that, in at least one embodiment, the invention does not utilize a reflecting element.

Therefore, there is no basis for the Examiner's rejection of claim 1 under either the first or second paragraph of 35 U.S.C. §112. Accordingly, Applicants respectfully request that the Examiner withdraw the §112 rejection of claim 1.

**Rejections under 35 U.S.C. §102**

Claim 1

Claim 1 recites:

An insertion device trajectory system, comprising:

an energy source for producing an energy path in a direction away from a medical insertion device thereby indicating any trajectory correction required for the insertion device; and

a mechanism by which the energy source can be attached to the insertion device.

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by each of U.S. Patent No. 4,657,012 to Burgin ("Burgin") and U.S. Patent No. 6,428,180 to Karram ("Karram").

The PTO provides in MPEP §2131 that

*"[t]o anticipate a claim, the reference must teach every element of the claim...."*

Therefore, to sustain this rejection with respect to claim 1, each of Burgin and Karram must contain all of the above claimed elements of the claim. However, as shown below Burgin and Karram do not contain all of the claimed elements of claim 1.

Burgin does not disclose an energy source that indicates trajectory corrections required for the insertion device. Rather, Burgin provides for “an instrument which the field upon which the instrument is to be used can be illuminated by the instrument.” The illumination in Burgin does not indicate any required trajectory corrections for the insertion device as required by claim 1.

Therefore, the §102(b) rejection of claim 1 is not supported by Burgin.

Similarly, Karram does not disclose an energy source that indicates trajectory corrections required for the insertion device. Rather, Karram focuses on lighting the operation site. The lighting in Karram does not indicate any required trajectory corrections for the insertion device as required by claim 1.

Therefore, the §102(b) rejection of claim 1 is not supported by Karram.

Thus, the §102(b) rejection of claim 1 is not supported by either of the Burgin or Karram references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 1.

#### Claims 3, 4, 6-9, 11, and 12

Claims 3, 4, 6-9, 11, and 12 were rejected under 35 U.S.C. §102(b) as being anticipated by Burgin (4,657,012). To sustain this rejection, Burgin must contain all of the claimed elements of claims 3, 4, 6-9, 11, and 12. However, as demonstrated above Burgin does not contain all of the claimed elements of claim 1. Claims 3, 4, 6-9, 11, and 12 depend from and further limit claim 1. Therefore, the §102(b) rejection of claims 3, 4, 6-9, 11, and 12 is not supported by the Burgin reference, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claims 3, 4, 6-9, 11, and 12.

Claim 5

Claim 5 was rejected under 35 U.S.C. §102(b) as being anticipated by Karram (6,428,180). To sustain this rejection, Karram must contain all of the claimed elements of claim 5. However, as demonstrated above Karram does not contain all of the claimed elements of claim 1. Claim 5 depends from and further limits claim 1. Therefore, the §102(b) rejection of claim 5 is not supported by the Karram reference, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 5.

Claim 13

Claim 13 recites:

A medical alignment device, comprising:

an energy source located on an insertion device wherein the energy source produces an energy path, wherein the energy path is reflected by a reflecting element; and  
a surface for indicating a location of the reflected energy path, so that the proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device.

Claim 13 was rejected under 35 U.S.C. §102(b) as being anticipated by each of Burgin (4,657,012) and Karram (6,428,180).

The PTO provides in MPEP §2131 that

*"[t]o anticipate a claim, the reference must teach every element of the claim...."*

Therefore, to sustain this rejection with respect to claim 13, each of Burgin and Karram must contain all of the above claimed elements of the claim. However, as shown below Burgin and Karram do not contain all of the claimed elements of claim 13.

Burgin does not disclose a surface for indicating any alignment correction required for the insertion device. Rather, Burgin provides for “an instrument which the field upon which the instrument is to be used can be illuminated by the instrument.” The illumination in Burgin does not indicate any required trajectory corrections for the insertion device as required by claim 13.

Therefore, the §102(b) rejection of claim 13 is not supported by Burgin.

Similarly, Karram does not disclose surface for indicating any alignment correction required for the insertion device, nor does Karram disclose a reflecting element as required by claim 13.

Therefore, the §102(b) rejection of claim 13 is not supported by Karram.

Thus, the §102(b) rejection of claim 13 is not supported by either of the Burgin or Karram references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 13.

#### Claims 14-16

Claims 14-16 were rejected under 35 U.S.C. §102(b) as being anticipated by Burgin (4,657,012). To sustain this rejection, Burgin must contain all of the claimed elements of claims 14-16. However, as demonstrated above Burgin does not contain all of the claimed elements of claim 13. Claims 14-16 depend from and further limit claim 13. Therefore, the §102(b) rejection of claims 14-16 is not supported by the Burgin reference, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claims 14-16.

#### Claim 18

Claim 18 recites:

A method of aligning a medical insertion device, the method comprising:  
generating an energy path from an energy source located on an insertion device;  
and  
reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device.

Claim 18 was rejected under 35 U.S.C. §102(b) as being anticipated by each of Burgin (4,657,012) and U.S. Patent No. 5,647,373 to Paltiel ("Paltiel").

The PTO provides in MPEP §2131 that

*"[t]o anticipate a claim, the reference must teach every element of the claim...."*

Therefore, to sustain this rejection with respect to claim 18, each of Burgin and Paltieli must contain all of the above claimed elements of the claim. However, as shown below Burgin and Paltieli do not contain all of the claimed elements of claim 18.

Burgin does not disclose reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device. Rather, Burgin provides for "an instrument which the field upon which the instrument is to be used can be illuminated by the instrument." The illumination in Burgin does not indicate any required trajectory corrections for the insertion device as required by claim 18.

Therefore, the §102(b) rejection of claim 18 is not supported by Burgin.

Similarly, Paltieli does not disclose reflecting the energy path so that a proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device as required by claim 18.

Therefore, the §102(b) rejection of claim 18 is not supported by Paltieli.

Thus, the §102(b) rejection of claim 18 is not supported by either of the Burgin or Paltieli references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claim 18.

#### Claims 19-21

Claims 19-21 were rejected under 35 U.S.C. §102(b) as being anticipated by Burgin (4,657,012) and Paltieli (5,647,373). Claim 19 was rejected under Burgin and Paltieli; claims 20 and 21 were rejected under Paltieli. Thus, to sustain this rejection, each of Burgin and Paltieli must contain all of the claimed elements of claim 19 and Paltieli must contain all of the claimed elements of claims 20 and 21. However, as demonstrated above Burgin and Paltieli do not contain all of the claimed elements of claim 18. Claims 19-21 depend from and further limit claim 18. Therefore, the §102(b) rejection of claims 19-21 is not supported by either of the Burgin or Paltieli references, and should be withdrawn. Accordingly, Applicants respectfully request the Examiner withdraw the §102(b) rejection of claims 19-21.

**Rejections Under 35 U.S.C. §103**

**Claim 10**

Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over Karram (6,428,180) in view of U.S. Patent No. 3,628,523 to Pirtle (“Pirtle”). Applicant traverses this rejection on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claim 10.

As the PTO recognizes in MPEP § 2142:

*... The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. If the Examiner does not produce a *prima facie* case, the Applicant is under no obligation to submit evidence of nonobviousness...*

It is submitted that, in the present case, the Examiner has not factually supported a *prima facie* case of obviousness for the following mutually exclusive reasons.

**1. Even when combined, the references do not teach the claimed subject matter**

As provided in 35 U.S.C. §103:

*A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains ... (Emphasis added)*

Thus, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. Examiner asserts that Karram discloses all aspects of claims 1. However, as illustrated above, Karram does not disclose all aspects of claim 1. Since neither Karram nor Pirtle teaches an energy source that indicates trajectory corrections required for the insertion device, as recited in claim 1, which claim 10 depends from and further limits, it is impossible to render obvious the subject matter of claim 10, as a whole, and the explicit terms of §103 cannot be met.

Thus, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 10. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 10 under 35 U.S.C. §103(a).

## **2. The combination of references is improper**

Assuming, arguendo, that the above argument for non-obviousness does not apply (which is clearly not the case based on the above), there is still another mutually exclusive and compelling reason why Karram and Pirtle cannot be applied to reject claim 10 under 35 U.S.C. §103(a). The MPEP provides in §2142 that:

*...the Examiner must step backward in time and into the shoes worn by the hypothetical 'person of ordinary skill in the art' when the invention was unknown and just before it was made....The Examiner must put aside knowledge of the Applicant's disclosure, refrain from using hindsight, and consider the subject matter claimed 'as a whole'.*

Here, neither Karram nor Pirtle teaches, or even suggests, the desirability of the combination since neither teaches an energy source that indicates trajectory corrections required for the insertion device as specified above and as recited in claim 1, which claim 10 depends from and further limits.

Thus, it is clear that neither reference provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 10.

In this context, the MPEP further provides at §2143.01:

*The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination.*

In the above context, the courts have repeatedly held that, absent some teaching, suggestion or incentive supporting combination, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention. In the present case, it is clear that the Examiner's combination arises solely from hindsight based on the invention and without any showing, suggestion, incentive, or

motivation in either reference for the combination as applied to claim 10. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 10. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 10 under 35 U.S.C. §103(a).

Claims 13 and 17

Claim 13 recites:

A medical alignment device, comprising:

an energy source located on an insertion device wherein the energy source produces an energy path, wherein the energy path is reflected by a reflecting element; and  
a surface for indicating a location of the reflected energy path, so that the proximity of the reflected energy path to the energy source indicates any alignment correction required for the insertion device.

Claims 13 and 17 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 5,598,269 to Kitaevich ("Kitaevich") in view of U.S. Patent No. 5,957,933 to Yanof ("Yanof"). Applicant traverses these rejections on the grounds that these references are defective in establishing a *prima facie* case of obviousness with respect to claim 13 and, therefore, claim 17 for the following mutually exclusive reasons.

**1. Even when combined, the references do not teach the claimed subject matter**

As described above, when evaluating a claim for determining obviousness, all limitations of the claim must be evaluated. However, since neither Kitaevich nor Yanof teaches an energy source located on an insertion device, as recited in claim 13, it is impossible to render obvious the subject matter of claim 13, as a whole, and the explicit terms of §103 cannot be met.

Thus, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 13. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 13 under 35 U.S.C. §103(a).

Further, since claim 17 depends from and further limits claim 13 the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 17 either. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 17 under 35 U.S.C. §103(a) as well.

**2. The combination of references is improper**

Assuming, arguendo, the above argument for non-obviousness does not apply (which is clearly not the case based on the above), there is still another mutually exclusive and compelling reason why Kitaevich and Yanof cannot be applied to reject claim 13 under 35 U.S.C. §103(a). That is, neither Kitaevich nor Yanof teaches, or even suggests, the desirability of the combination since neither teaches an energy source located on an insertion device as specified above and as recited in claim 13.

Thus, it is clear that neither reference provides any incentive or motivation supporting the desirability of the combination. Therefore, there is simply no basis in the art for combining the references to support a 35 U.S.C. §103(a) rejection of claim 13.

In this context, the courts have repeatedly held that, absent some teaching, suggestion or incentive supporting combination, obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention. In the present case, it is clear that the Examiner's combination arises solely from hindsight based on the invention and without any showing, suggestion, incentive or motivation in either reference for the combination as applied to claim 13. Therefore, for this mutually exclusive reason, the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 13. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 13 under 35 U.S.C. §103(a).

Further, since claim 17 depends from and further limits claim 13 the Examiner's burden of factually supporting a *prima facie* case of obviousness has clearly not been met with respect to claim 17 either. Therefore, Applicants respectfully request Examiner withdraw the rejection of claim 17 under 35 U.S.C. §103(a) as well.

**Rejections under Double Patenting**

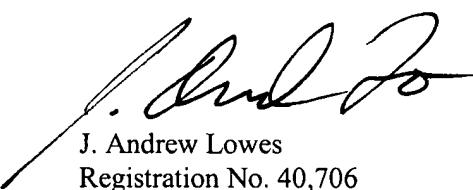
Claims 1 and 3-21 were rejected under the judicially created doctrine of obviousness-type double patenting. A terminal disclaimer is submitted with this Response. Accordingly, claims 1 and 3-21 are in condition for allowance.

Conclusion

It is clear from all of the foregoing that independent claims 1, 13, and 18 are in condition for allowance. Dependent claims 3-12, 14-17, and 19-21 depend from and further limit independent claims 1, 13, and 18 and, therefore, are allowable as well.

It is believed that all matters set forth in the Office Action have been addressed, and that claims 1 and 3-21 are in condition for allowance. Favorable consideration and an early indication of the allowability of the claims are respectfully requested. Should the Examiner deem that an interview with Applicant's undersigned attorney would expedite consideration, the Examiner is invited to call the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



J. Andrew Lowes

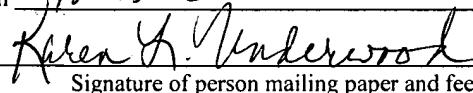
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